

PSJ3

Exhibit 301

UPDATE ON ORDER MONITORING AND RETAILER DUE DILIGENCE

CPPC Meeting

July 9, 2013

Steve Seid

Executive Director

National Accounts & Trade Relations

Cardinal Health to pay civil fine for drug-distribution violations

By [Mike Pramik](#)

THE COLUMBUS DISPATCH Thursday October 2, 2008 10:47 PM

Cardinal Health has reached a settlement with the U.S. Drug Enforcement Administration and seven U.S. attorney's offices that will allow it to resume shipments of controlled substances from all its warehouses.

The Dublin drug distributor agreed tonight to pay \$34 million in civil penalties in response to allegations that it violated provisions of the Controlled Substances Act, which governs the distribution of certain addictive drugs. The DEA alleged that Cardinal failed to notify the federal agency of suspicious shipments of drugs such as hydrocodone, commonly sold as Vicodin, to pharmacies that later illegally sold the medication over the Internet.



September 12, 2012

Contact: Public Information Officer

Number: 954-660-4602

DEA Revokes Two CVS Retailers' Ability To Sell Controlled Substances

MIAMI, FL. – Mark R. Trouville, Special Agent in Charge of the Miami Field Division, Drug Enforcement Administration (DEA), announced today the revocation of DEA Registrations at two CVS Pharmacies located in Sanford, Florida. This action marks the first time the DEA has revoked the registration of a registrant that is part of a large national chain.

FOR IMMEDIATE RELEASE
Date: May 15, 2012
Contact: DEA Public Affairs
Number: 202-307-7977

**DEA Suspends for Two Years Pharmaceutical Wholesale Distributor's
Ability to Sell Controlled Substances from Lakeland, Florida Facility**

In the agreement, Cardinal admits that it's due diligence efforts for some pharmacy customers and its compliance with an earlier MOA signed in 2008 for similar violations at the same facility were, in certain respects, inadequate. The terms of the agreement of this settlement represent a complete resolution of this administrative matter; however, the MOA expressly reserves the right for DEA to pursue civil penalties. The obligations in this MOA remain in full force and effect for a period of five years unless DEA agrees in writing to an earlier termination.

"The Drug Enforcement Administration is committed to battling the prescription drug abuse epidemic in this country at all levels, from corporate America to pill mills. Regardless of the size of a company or its profitability, organizations that fail to prevent the diversion of powerful controlled substances will be held accountable," said Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control. "Cardinal Health is not above the law, and with this agreement it admits that it neglected its vital responsibility to prevent the diversion of controlled substance

On February 3 of this year, DEA's Miami Field Division served an Immediate Suspension Order (ISO) against Cardinal Health's distribution center at 2045 Interstate Drive in Lakeland, Florida, alleging that this distribution center failed to maintain effective controls against the diversion of controlled substances, specifically oxycodone. In just three years, Cardinal's Lakeland center supplied more than 12 million dosage units of oxycodone, a highly addictive, powerful painkiller, to four area pharmacies. Over the past several years, Florida has been at the epicenter of the nationwide prescription drug abuse epidemic. Various illicit schemes operating in Florida, and those who supply them, have been responsible for the diversion of millions of dosage units of prescription drugs containing oxycodone or hydrocodone that are in turn redistributed along the entire eastern seaboard and parts of the Midwest.



FOR IMMEDIATE RELEASE

Contact: DEA Public Affairs

(202) 307-7977

Press Release



WALGREENS AGREES TO PAY A RECORD SETTLEMENT OF \$80 MILLION FOR CIVIL PENALTIES UNDER THE CONTROLLED SUBSTANCES ACT

Largest Fine Paid by a DEA Registrant

JUN 11 – (MIAMI) – Today DEA Miami Field Division Special Agent in Charge Mark R. Trouville and the United States Attorney for the Southern District of Florida announced that Walgreens Corporation (Walgreens), the nation's largest drug store chain, has agreed to pay \$80 million in civil penalties, resolving the DEA's administrative actions and the United States Attorney's Office's civil penalty investigation regarding the Walgreens Jupiter Distribution Center and six Walgreens retail pharmacies (collectively "Registrants") in Florida. The settlement further resolves similar open civil investigations in the District of Colorado, Eastern District of Michigan, and Eastern District of New York, as well as civil investigations by DEA field offices nationwide, pursuant to the Controlled Substances Act (the Act).

DEA Activity

- DEA is offering Pharmacy Diversion Awareness Conferences
 - One day programs
 - Goal: “The conference is designed to assist pharmacy personnel in identifying and responding to potential diversion activity.”
- Joseph T. Rannazzisi
 - Deputy Assistant Administrator, Office of Diversion Control ,DEA
 - Testified in front of Committee of Homeland Security
 - Among other things he stated that:
 - “The last line of defense against diversion is the pharmacist”
 - He also noted the expansion of Tactical Diversion Squads
 - These squads will investigate diversion schemes , noting doctor shopping & Rx forgery rings. As well as practitioners, or pharmacists , who divert controlled substances

KEY PROVISIONS OF THE CONTROLLED SUBSTANCES ACT (CSA)

- 21 CFR 1301.74(b)
 - Specifically requires the registrant “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”
 - Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substance was being diverted.
- 21 CFR 1304.6(a):Rule of Corresponding Responsibility
 - (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

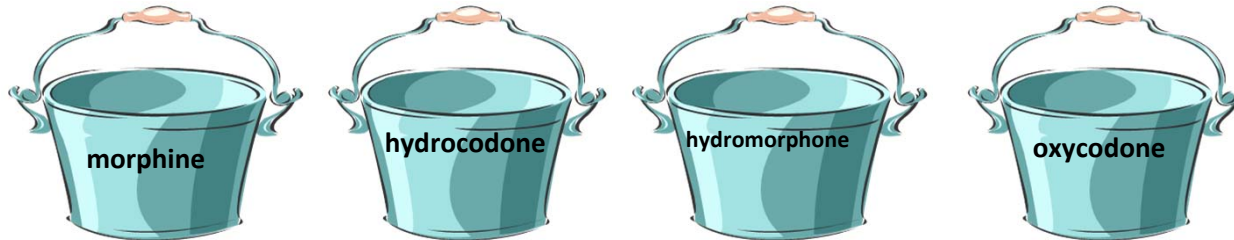
From The DEA Pharmacist Manual

(Revised 2010)

- **“A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. Such action is a felony offense, which may result in the loss of one’s business or professional license (see United States v. Kershman, 555 F.2d 198 [United States Court Of Appeals, Eighth Circuit, 1977]). “**

ORDER MONITORING IMPACT

- Possible reduction/limitation of supply
 - Outlet order quantity limits and ceilings have been implemented by wholesalers
 - Products are put into categories or “buckets” by molecule
 - Wholesaler and retailer implementing conservative approaches
 - Suspected doctor shopping



- The fading secondary wholesaler
 - Wholesaler and retailer conservative approach
- Purdue's Order Monitoring System Committee (suspicious orders)
 - Multi-disciplinary team
 - VP Associate General Counsel, Director OMS, VP Corporate Security, Exec Dir National Accounts, Dir. of Investigations and RXP, Ex. Dir., Controlled Sub Act Compliance
 - Collaboration with industry

Major Pharmacy Retailers Currently Implementing
“Corresponding Responsibility Programs”
(patient vetting)

- Walgreens
- CVS
- Rite Aid
- Walmart
- Kroger (and affiliates)
- Costco
- Safeway

Note: Approximately 65% of all Rx's nationally are dispensed in these accounts



Dear Valued Prescriber,

Walgreens wants to ensure that our patients continue to have access to the medications they need while fulfilling our role in reducing the potential abuse of controlled substances. Our intent is to partner with you to ensure that patients receive their appropriate therapy and that the necessary information to confirm the appropriateness of the prescription is documented to satisfy DEA requirements. This process is designed to protect both you and the pharmacist.

According to Title 21 of the Code of Federal Regulations, section 1306.04, pharmacists are required by the DEA regulations to ensure that prescriptions for controlled substances are issued for a legitimate medical purpose. The regulation states the following:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Our pharmacists are required to take additional steps when verifying certain prescriptions for controlled substances. This verification process may, at times, require the pharmacist to contact you for additional information necessary to fill the prescription. While the information requested may vary, potential questions could include information about the diagnosis, ICD-9 code, expected length of therapy and previous medications/therapies tried and failed. Privacy laws allow you to share this information with another healthcare professional who is providing care to the patient.

We realize that this process may generate questions and concerns from both you and the patient and we will do our best to respond in a professional and courteous manner. We recognize that sharing appropriate information with our pharmacists may require additional time from you or your office staff and we want to thank you in advance for partnering with us to provide the best care to our patients.

Be well,

Your Walgreens Pharmacist

Sent to physicians
April 2013

Overview of Retailer Programs

- Range from detailed checklists to individual pharmacist clinical decision (or own discretion)
- Most programs incorporate DEA “Red Flags” such as cash payers, large quantities, multiple meds...
- Walgreens and CVS appear to have the most detailed programs
- There is a National Association of Chain Drug Stores (NACDS) “retailer task force” looking to establish industry wide guidelines, in addition to working with the Pain Forum

Purdue's National Accounts Team

Activity with the Trade

- In June met with the three major wholesalers (Amerisource Bergen Corp (ABC), McKesson, and Cardinal) to discuss these issues
- Also a topic with Regional Wholesalers (HD Smith, JM Smith, Burlington, Miami Lukin)
- Wholesalers are becoming more conservative and taking action independent of the chains and independent pharmacies they supply
 - Both “Smiths” have closed accounts and continue their tight scrutiny
 - JM Smith YE 2010 vs. YE 2012 down \$12+M or -24% in sales. Through 6/13 down -8%
 - HD Smith YE 2010 vs. YE 2012 down \$37M or -42% in sales/ Through 6/13 -28%
 - Burlington Drug has hired a consultant to help them develop tighter guidelines
 - McKesson SVP reported that they “closed their top 15 pharmacy accounts”
 - “A unilateral decision with-out discussion”
 - McKesson's Denver Distribution Center is currently under investigation
 - ABC expects Walgreens to adhere to their (ABC's) threshold policies

Purdue's National Accounts Team Activity with the Trade

- Steve Seid has met, or been in contact with, senior management at Walgreens, Rite Aid, Walmart, and Stop and Shop/Giant
 - Attempts to meet with CVS have not yet been successful
- National Account Managers have been in contact with Costco, Safeway, and Kroger

Purdue's National Accounts Team

Activity with the Trade

- Walgreens Meeting
 - Numerous Walgreens personnel at the meeting. Rex Swords, Div. VP of Pharmacy Services reviewed their program with Purdue.
 - The “Good Faith Dispensing Policy ”is based on their interpretation of the general guidelines in the Controlled Substance Act.
 - This is a manual process. The almost 24,000 pharmacists are trained to take specific steps prior to dispensing an opioid. All of the steps are documented, the patient record is annotated.
 - Pharmacist judgment is required. The questions asked do not provide the pharmacist with a yes or no answer. They are directed to rely on their clinical judgment to make the dispensing decision.
 - They look at eight different criteria:
 - Such as; is this a known patient? Paying cash? Out of area? Etc.
 - The pharmacist is required to review the state Prescription Monitoring Program, if available.
 - If a pharmacist is “on the fence” as to whether to deny the Rx, the pharmacist is to call the physician to validate the validity of the prescription.
 - They do ask about overall therapy, other meds, what tests were done, diagnosis, etc.
 - They are not supposed to ask to see these items, i.e. an MRI or x-ray.

Purdue's National Accounts Team

Activity with the Trade

- Walgreens (continued)
 - All opioids are included, but the focus is now on oxycodone, hydromorphone, and methadone prescriptions
 - Rex conceded that overzealous pharmacists can be an issue. He said rhetorically “Are they calling too much? Probably yes.”
 - He indicated that on average this interaction is 5 to 6 times per week, at the average store
 - They have heard the complaints and blow back from physicians and customers/patients.
 - They have been in contact with the AMA and AAFP. They have presented to state physician associations. They have met with, and been in contact with, government representatives
 - They indicated that Walgreens representatives are listening, but telling those they meet with that they are sensitive to the issues, but are not backing away from the Good Faith Dispensing Initiative
 - In a separate conversation the program director said corporate would not override a bench pharmacist's decision
 - Purdue's SOMS has a follow up meeting scheduled in July

Purdue's National Accounts Team Activity with the Trade

- Rite Aid
- Met with Dan Miller, SVP of Pharmacy
- The Rite Aid policy is centered around the pharmacist following corporate guidelines and relying on their clinical judgment
- They target “high risk” molecules: Oxycodone, hydromorphone, hydrocodone and morphine
- Unknown (new) patients get a significant level of scrutiny
- All interaction is documented
- Rite Aid patient profile is checked to ascertain other products taken and their utilization of other stores
- Review of PMP is required in those states with a program

Purdue's National Accounts Team Activity with the Trade

- Rite Aid (continued)
 - The pharmacist is trained on the typical red flag areas
 - If after going through all of the review the pharmacist is still uncomfortable they are to contact the physician to discuss diagnosis
 - The bench pharmacist ultimately makes the “fill/don’t fill” decision
 - Corporate will not overrule the pharmacist decision

Purdue's National Accounts Team Activity with the Trade

- Follow up call is set with Walgreens
- Second contact with Walmart being set
- Call on CVS being set
- Will be a main focus of discussions on all contacts at the NACDS "Total Store Expo" in August
 - Reach out to NACDS
- NAMS discuss on all regional chain calls
 - For example Bartells
- Meetings with wholesaler Suspicious Order Monitoring teams to discuss thresholds
- Working with Dave Rosen on a study to utilize with the trade on what an appropriate patient "looks like"

Purdue's National Accounts Team Activity with the Trade

- Enhanced pharmacist education
 - Working with marketing on “*Learn Something*” pharmacist network training module(s)
 - Broad distribution of the OxyContin Pharmacist Guide.
 - For Example:
 - Sent electronically within Walmart and Shopko
 - Hard copy sent to 1000+ JM Smith customers, delivered by Harris Teeter to 152 stores
- Working to find a way to utilize store level wholesaler data to provide product availability information for patients
- Exploring other options for enhanced patient access

Conclusions

- This activity has significantly increased in the past three months
- Driven by DEA actions, DOJ fines and ongoing investigations
- An ultra-conservative approach is being taken by wholesalers and pharmacies
- This may get worse before it gets better
 - More pharmacies (independents)
 - More automated so every RX gets scrutinized via the computer system
- Inventory across supply chain decreasing
- New patients being impacted due to quantity limits implemented by wholesalers (based on previous ordering history).
 - These limits also impact continuing patients who have Rxs filled towards end of the month.
 - Also hearing of overflow into stores who have inventory causing them to run out early and unable to obtain more product before the next months and next “allotment”
- Legitimate patients caught in the “cross fire” and unable to get the medication they need